IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Patrick RAMBAUD	Conf. 1794
Application No. 10/687,636	Group 1631
Filed October 20, 2003	Examiner P. Whaley

METHOD AND SYSTEM FOR MANAGING BATCHES OF IMMUNOCOMPETENT CELLS COLLECTED FROM HUMAN OR ANIMAL SUBJECTS FOR DEFERRED USE, AND RELATEDTHERAPY METHODS

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

Applicant requests a pre-appeal brief review of the final rejection in the above-identified application. No amendments are being filed with this request.   A Notice of Appeal is filed herewith.

Respectfully submitted,

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November 15, 2011

REASONS IN SUPPORT OF REQUEST FOR REVIEW

A pre-appeal brief review is respectfully requested as to claims 33 and 36 which stand rejected under 35 U.S.C. 103(a) over Lefesvre et al. (WO/1999/053030), in view of Winkel (Clinical Chemistry, 1989, 35/8, p.1595-1600), and in view of Adrion et al. (US 5,023,785).

I. Applicant notes that the Examiner has different interpretations of Lefesvre in two different Official Actions. In the Official Action of 11/12/2010 (page 10) the Examiner clearly states that "**Lefesvre doesn't teach** an expert system that determines deferred-use protocol comprisingbiological and technical indications required for cell processing" whereas in the Official Action of 08/10/2011 (page 8) the Examiner states "**Lefesvre doesn't specificallv teach** implementing deferred use protocols comprising biological and technical indications required for cellprocessing. However **Lefesvre** suggests this limitation".

II - Non-obviousness of Claims 33 and 36

In addition to the above, the Examiner recognizes (page 10 ofthe Official Action) that Lefesvre doesn't teach:

i) an expert system that applies a set of rules stored in a knowledge base; or

ii) parameters of deferred-use protocol that include optimal proportions of various selected cell types using the subject's immunity data.

1) Winkel

The rejection states that Winkel discloses an expert system using rules for producing diagnostic results and treatment recommendations. (page 10 of Official Action). From there, the Examiner states that "it would have been obvious to someone of the ordinary skill in the art to modify the cellular re-use processing center of Lefesvre to include an expert system thatapplies a set of rules stored in a knowledge system".

No objective evidence supports this conclusion, and therefore there is no factual/legal support for a finding of obviousness.

Winkel teaches several expert systems applied to clinical data. Some of the expert systems disclosed in Winkel provide diagnostic results and treatment recommendations. At page 1597 col. 2, Winkel discloses a table listing the most known expert systems emphasizing the use of laboratory data. However, none of the expert systems listed in this table is used in the domain of the reuse of cells, or the processing of parameters of a cell re-use protocol.

Moreover, the Examiner states that it would have been obvious "to include an expert system that applies <u>a set of rules stored in a knowledge system</u>". However, the Examiner doesn't address: which set of rules stored in which knowledge system? Indeed, none of the rules used in any of the expert

systems described in Winkel is applicable to cell re-use protocol determination. So, when including an expert system in a re-use processing center in order to determine cell re-use protocol parameters, a person having ordinary skills in the art has to define the set of rules which are not taught in Winkel. This is not an ordinary operation and is not obvious for an ordinary skilled person. Further, the Examiner has not shown otherwise.

Moreover, Winkel repeatedly states that the adaptation of an expert system designed for a given domain for use in a different domain is very difficult and can only be done if the requirements imposed by the problem are understood (see p.1597 col. 2 §3, p. 1598 col. 1 §2 §3 "the appropriate tool can be chosen only after requirements imposed by the problem are understood").

Finally, Winkel states as a conclusion that "the development of transparent systems ... that may be transferred between technical and medical environments and easily updated and modified by the end user **represents a real challenge**"(p.1599,col. 2, §2). This sentence means that transferring an expert system of Winkel designed for the environment of treatment recommendations to cell reuse environment "represents a real challenge". This is objective evidence that the adaptation of the expert systems of Winkel for use in the domain of the reuse of cells is not obvious.

2) Adrion

Adrion teaches an expert systems outputting diagnostic information of a patient. In claim 4, Adrion discloses the name of the parameters taken into account in the diagnostic. The rejection states that Adrion teaches optimized parameters comprising the cell ratio amounts based on claim 1 and claim 4 (see Official Action page 10, lines 12-16).

Applicant respectfully disagrees as the Examiner has misinterpreted Adrion. Adrion teaches an expert system outputting diagnostic information of a patient in the domain of hematology. However, the apparatus disclosed in Adrion comprises data processing means for "evaluating blood derived parametric values" and "means for "ascertaining clinically interval combination". Adrion doesn't determine optimal proportions of cell types, but only combination of intervals. In Adrion claim 4, the expression "Iymphocyte/monocyte count" doesn't mean the ratio of lymphocyte/monocyte. Rather, the expression "lymphocyte/monocyte count" means "lymphocyte **or** monocyte count".

This interpretation is confirmed in Adrion claim 5 where it is stated that the " ... Iymphocyte/monocyte count ... is expressed in x109/L". Indeed, if it was theratio the count wouldn't be expressed in "/L" and wouldn't have any measurement unit. At least for these reasons, Adrion doesn'tdisclose "determining parameters of deferred-use

protocol including optimal proportions of various selected cell types using the subject's immunity data". Thus, Adrion also doesn't disclose feature ii (parameters of deferred-use protocol that include optimal proportions of various selected cell types using the subject's immunity data).

3 - Conclusions

From the above, it is shown that:

it is not obvious to include the expert system of Winkel in the cell processing center of Lefesvre, in order to reach to an expert system that applies a set of rules stored in a knowledge base in order to determine a cell re-use protocol; and

Adrion doesn't teach feature ii).

Moreover, the abovefurther shows that there is objective evidence in Winkel that the transfer of an expert system designed for a given domain to a differentdomain is not obvious for a person having ordinary skills in the art and rather represents a real challenge.

Accordingly, Applicantrespectfully submits that neither independent claim 33 nor claim 36 is rendered obvious by Lefesvre in view of Winkel and Adrion.The Declaration of Professor Dominique CHARRON provides further evidence of the claims being non-obvious.

The rejection of claims 33 and 36 is based on both factual and legal error and should therefore be withdrawn.